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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/634,207 | 08/09/2000 | Dennis A. Carson | 103.022US1 | 4171 |

21186 7590 01/14/2004

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

TRUONG, TAMTHOM NGO

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/634,207

Applicant(s)

CARSON ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 12-23, and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 12-23, and 49-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 8-25-03 has been entered.

Claims 1-9, 11, and 24-48 have been cancelled, leaving claims 10, 12-23, and 49 remaining for consideration along with new claims 50-54.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10, 12-23, and 49-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claims 1 and 49 recite the limitation of "*amino acid ester of (ω -(OH)(C₂-C₄))alkoxy, ..., or OCH₂CH₂N(CH₃)₃⁺*" [emphasis added]. However, it is noted that the groups (ω -(OH)(C₂-C₄))alkoxy and OCH₂CH₂N(CH₃)₃⁺ are not amino acid esters. The

group of $(\omega-(OH)(C_2-C_4))alkoxy$ is a hydroxy substituted alkoxy group, and not an ester group. Likewise, the group of $OCH_2CH_2N(CH_3)_3^+$ is a quaternary ammonium substituted alkoxy group, and not an ester group. Thus, the metes and bound of “amino acid ester” is indefinite because it includes groups that are not accepted by the meaning of ester known in the art. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term.

Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

b. Claims 12-23, and 50-54 are rejected as being dependent on claims 1 and 49, and carrying over the limitation of “amino acid ester”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Enablement:** Claims 10, 12-23, and 49-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

a. The breadth of the claims: Claims 1 and 49 recite methods of treatment of certain cancers (e.g., leukemia, multiple myeloma, bone marrow, etc.) comprising administering an effective amount of a compound of formula (I) wherein Y-Z represents a complicated side chain of an extensively substituted alkoxy, an amino acid ester, and even contains a quaternary ammonium. Thus, the chemical structure of formula (I) is far more complicated than Etodolac, which is a compound that the claimed formula I derived from.

b. The amount of direction or guidance presented: For the preparation of the claimed formula (I), the specification simply refers to **Demerson et. al.** (US 3,843,681).

However, in that patent, the compounds have a side chain of a simple acid or amide which is not further substituted, or containing a quaternary ammonium. Thus, to make a compound of the claimed formula (I), one would have to extensively modify the teaching of **Demerson et. al.** Different starting materials would be needed for the instant Y-Z. Likewise, different reaction conditions would be required also, especially for a group such as: an amino acid ester, or a group having a quaternary ammonium.

Furthermore, Etodolac is the only compound tested for activity in treating cancers. However, the claimed methods of treatment do not use Etodolac. Since the side chain of Etodolac is only a simple acid of $-\text{CH}_2\text{COOH}$, the activity of Etodolac cannot be extrapolated to compounds of the claimed formula (I) which has a more complicated side chain.

c. **The state of the prior art:** Aside from Etodolac, the state of the art (as evident by US'681, or any prior arts of record) has not taught a method of treating any of the cancers claimed herein by administering a compound of the claimed formula (I). In fact, even the closest compound such as Etodolac-glucuronide has not been shown to have activity for treating any cancers.

Thus, with the **unpredictable nature of the art**, and the limited guidance, the skilled chemist would have to carry out undue experimentation to make and use compounds of the instant formula (I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthorn N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1st -03.

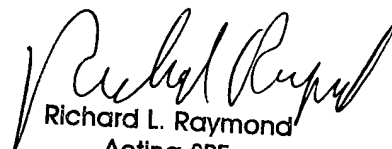
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

January 7, 2004



Richard L. Raymond

Acting SPE

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